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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1267]

Draft Guidance for Industry on NDA's: Impurities in Drug Substances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''NDA's: Impurities in Drug Substances.'' This draft document recommends that applicants submitting new drug applications (NDA's) and holders of supporting Type II drug master files (DMF's) for drug substances not considered new drug substances refer to the guidance for industry on reporting drug substance impurities in the International Conference on Harmonisation (ICH) guidance document entitled ''Q3A Impurities in New Drug Substances.''

DATES: Written comments on the draft guidance document may be submitted by (*insert date 90 days after date of publication in* **Federal Register**). General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Eric P. Duffy, Office of New Drug Chemistry, Office of Pharmaceutical Science, Center for Drug Evaluation and Research (HFD–180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7310.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''NDA's: Impurities in Drug Substances.'' Although ICH guidance document entitled ''Q3A Impurities in New Drug Substances,'' which was published in the **Federal Register** on January 4, 1996 (61 FR 371), provided guidance to industry on the reporting, identification, and qualification of impurities in new drug substances produced by chemical syntheses, FDA believes that the guidance provided in ICH Q3A also applies to drug substances produced by chemical syntheses that are not considered new drug substances. FDA recommends that applicants preparing NDA's and holders preparing Type II DMF's refer to the reporting information contained in that document.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on reporting impurities in drug substances for certain NDA's and DMF's. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except

that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 1999

January 13, 1999

William K. Hubbard
Associate Commissioner
for Policy Coordination

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Jen Windsor

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